

COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, VA 22313-1450

Docket No.: 200.1113CON2  
Date: July 1, 2004

IFW



In re application of: Philip J. PALERMO, et al.  
Serial No.: 10/665,735  
Filed: September 18, 2003  
For: **A METHOD OF PREVENTING ABUSE OF OPIOID DOSAGE FORMS**

Sir:

Transmitted herewith is an **Information Disclosure Statement** in the above-identified application.

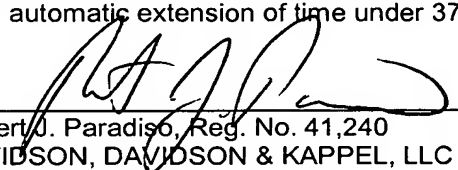
- ☐ Small entity status of this application under 37 C.F.R. 1.9 and 1.27 has been established by a verified statement previously submitted.
- ☐ A verified statement to establish small entity status under 37 C.F.R. 1.9 and 1.27 is enclosed.
- ☐ No fee for additional claims is required.
- ☐ A filing fee for additional claims calculated as shown below, is required:

		(Col. 1)	(Col. 2)	SMALL ENTITY		OR	LARGE ENTITY	
FOR:	REMAINING	HIGHEST		RATE	FEE		RATE	FEE
	AFTER	PREVIOUSLY	PRESENT					
	AMENDMENT	PAID FOR	EXTRA					
TOTAL CLAIMS	* Minus 20** =			x \$ 9	\$		x \$ 18	\$
INDEP. CLAIMS	* Minus 3*** =	0		x \$ 42	\$		x \$ 84	\$
<input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEP. CLAIM				+ \$140	\$		+ \$280	\$

TOTAL: \$ OR TOTAL: \$

- \* If the entry in Co. 1 is less than the entry in Col. 2, write "0" in Col. 3.
- \*\* If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, write "20" in this space.
- \*\*\* If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, write "3" in this space.

- ☒ Also transmitted herewith are:
- ☐ Petition for extension under 37 C.F.R. 1.136 (in duplicate)
- ☒ Other: PTO form 1449 (24 pages).
- ☐ Check(s) in the amount of \$ .00 is/are attached to cover:
- ☐ Filing fee for additional claims under 37 C.F.R. 1.16
- ☐ Petition fee for extension under 37 C.F.R. 1.136
- ☐ Other:
- ☐ The Assistant Commissioner is hereby authorized to charge payment of the following fees associated with this communication or credit any overpayment to Deposit Account No. 50-0552.
- ☐ Any filing fee under 37 C.F.R. 1.16 for the presentation of additional claims which are not paid by check submitted herewith.
- ☐ Any patent application processing fees under 37 C.F.R. 1.17.
- ☐ Any petition fees for extension under 37 C.F.R. 1.136 which are not paid by check submitted herewith, and it is hereby requested that this be a petition for an automatic extension of time under 37 CFR 1.136.

  
Robert J. Paradiso, Reg. No. 41,240  
DAVIDSON, DAVIDSON & KAPPEL, LLC  
485 Seventh Avenue, 14<sup>th</sup> Floor  
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Fax: (212) 736-2427

I hereby certify that this correspondence and/or documents referred to as attached therein and/or fee are being deposited "via hand delivery" in an envelope addressed to "Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" on July 1, 2004.

DAVIDSON, DAVIDSON & KAPPEL, LLC

BY: \_\_\_\_\_



200.1113CON2

**UNITED STATES PATENT AND TRADEMARK OFFICE**

Examiner: To be determined; Art Unit: 1614

Re: Application of: Philip J. PALERMO et al.  
Serial No.: 10/665,735  
Filed: September 18, 2003  
For: **A METHOD OF PREVENTING ABUSE OF OPIOID  
DOSAGE FORMS**

**INFORMATION DISCLOSURE**  
**STATEMENT UNDER 37 C.F.R. § 1.56**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

July 1, 2004

Sir:

In accordance with the provisions of 37 C.F.R. § 1.97, Applicants hereby make of record the documents listed on the accompanying Form PTO-1449 (24 sheets) for consideration by the Examiner in connection with the examination of the above-identified patent application.

Pursuant to 37 C.F.R. § 1.98 (a), the foreign patent documents and non-patent references listed on sheets 1-24 of the attached Form PTO-1449 are enclosed. If it is determined that any of the listed references are not of record in the parent application or presently enclosed, the Examiner is requested to contact the undersigned so that a copy can be forwarded.

Applicants also respectfully advise the Examiner of the following U.S. Patents and co-pending U.S. Patent Applications which are commonly assigned to the owners of the instant application:

U.S. Application Serial No. 09/992,936, entitled "Opioid Agonist/Opioid Antagonist Acetaminophen Combination", filed November 5, 2001, which is a continuation of U.S. Application Serial No. 09/503,020 filed February 11, 2000 entitled "Opioid Agonist/Opioid

Antagonist/Acetaminophen Combinations”, now U.S. Patent No. 6,375,957, issued April 23, 2002, which is a continuation in part of U.S. Application Serial No. 09/218,662, “Opioid Agonist/Antagonist Combinations”, filed December 22, 1998, now U.S. Patent No. 6,277,384, issued August 21, 2001, listed as reference WG on the attached Form PTO-1449;

U.S. Application Serial No. 10/694,559, entitled “Opioid Agonist/Antagonist Combinations”, filed October 27, 2003, which is a continuation of U.S. Application Serial No. 10/244,783, now U.S. Patent No. 6,696,066, issued February 24, 2004, which is a continuation of U.S. Application Serial No. 09/815,167, now U.S. Patent No. 6,475,494, issued November 5, 2002, which is a continuation of U.S. Application Serial No. 09/218,662, now U.S. Patent No. 6,277,384, issued August 21, 2001;

U.S. Application Serial No. 10/747,865, entitled “Controlled Release Compositions Containing Opioid Agonist and Antagonist”, filed December 29, 2003, which is a continuation of U.S. Application Serial No. 09/781,076, now U.S. Patent No. 6,716,449, issued April 6, 2004, listed as reference XJ on the attached Form PTO-1449;

U.S. Application Serial No. 10/689,866 filed October 21, 2003; 10/701,041 filed November 4, 2003; 10/700,861 filed November 4, 2003; 10/700,893 filed November 4, 2003; and 10/700,906 filed November 4, 2003, which are all continuations of U.S. Application Serial No. 09/781,081, entitled “Tamper-Resistant Oral Opioid Agonist Formulations”, now U.S. Patent No. 6,696,088, issued February 24, 2004; listed as reference XK on the attached Form PTO-1449.

U.S. Application Serial No. 10/213,919, entitled “Opioid Agonist Formulations with Releasable and Sequestered Antagonist”, filed August 6, 2002;

U.S. Application Serial No. 10/214,408, entitled “Sequestered Antagonist Formulations”, filed August 6, 2002;

U.S. Application Serial No. 10/199,972, entitled “Pharmaceutical Combinations of

Oxycodone and Naloxone”, filed July 18, 2002; and

U.S. Application Serial No. 10/389,238, entitled “Naltrexone Hydrochloride Compositions”, filed March 14, 2003.

The Examiner’s attention is directed to the following references of record, which were cited by the Examiner during the prosecution of grandparent U.S. Application Serial No. 09/218,663, filed December 22, 1998, now U.S. Patent No. 6,228,863:

**QC** (U.S. Patent No. 5,624,932 to Qin et al.);  
**QD** (U.S. Patent No. 5,633,259 to Qin et al.);  
**MC** (U.S. Patent No. 5,472,943 to Crain et al.);  
**ND** (U.S. Patent No. 5,512,578 to Crain et al.);  
**PB** (U.S. Patent No. 5,580,876 to Crain et al.);  
**RF** (U.S. Patent No. 5,767,125 to Crain et al.);  
**SG** (U.S. Patent No. 5,866,164 to Kuczynski et al.); and  
**AU** (Walsh et al.).

Pursuant to 37 C.F.R. § 1.98 (a)(2)(iii), the Examiner’s attention is also directed to **Exhibit A**, attached herewith, which contains the following:

(i) the claims of pending U.S. Application Serial No. 09/992,936, which has the same specification as U.S. Patent No. 6,375,957, listed as reference XE on the attached Form PTO-1449;

(ii) the claims of pending U.S. Application Serial No. 10/694,559, which has the same specification as U.S. Patent No. 6,696,066, listed as reference XL on the attached Form PTO-1449;

(iii) the claims of pending U.S. Application Serial No. 10/747,865, which has the same

specification as U.S. Patent No. 6,716,449, listed as reference XJ on the attached Form PTO-1449;

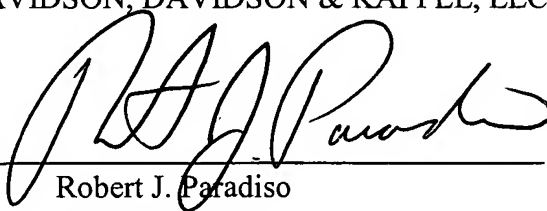
(iv) the claims of pending U.S. Application Serial Nos. 10/689,866; 10/701,041; 10/700,861; 10/700,893; and 10/700,906, which have the same specification as U.S. Patent No. 6,696,088, listed as reference XK on the attached Form PTO-1449; and

(v) the specifications and claims for pending U.S. Applications Serial Nos. 10/213,919, 10/214,408, 10/389,238 and 10/199,972 .

It is respectfully requested that the references cited in the accompanying Form PTO-1449 (24 sheets) be considered and made of record.

This Information Disclosure Statement is filed under 37 C.F.R. § 1.97 (b), before the mailing of a first Office Action on the merits. Accordingly, no fee is believed due. In the event any additional fee is due or any overpayment made in connection with the filing of this Information Disclosure Statement, the Commissioner is hereby authorized to charge said deficiency or credit overpayment to our Deposit Account No. 50-0552.

Respectfully submitted,  
DAVIDSON, DAVIDSON & KAPPEL, LLC

By   
Robert J. Paradiso  
Reg. No. 41,240

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New York, New York 10018  
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FORM PTO-1449 (REV 7-99)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO.: 200.1113CON2		SERIAL NO.: 10/665,735								
<b>LIST OF PRIOR ART CITED BY APPLICANT</b> (Use several sheets if necessary)				APPLICANT(S): Philip J. PALERMO et al.										
				FILING DATE: September 18, 2003		GROUP: 1614								
U.S. PATENT DOCUMENTS														
*EXAMINER INITIAL		DOCUMENT NUMBER							DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
	AA	2	7	7	0	5	6	9	11/56	Fromherz et al.	167	65		
	AB	3	1	3	3	1	3	2	05/12/64	Loeb, et al.	264	49		
	AC	3	1	7	3	8	7	6	03/16/65	Zobrist	252	137		
	AD	3	2	7	6	5	8	6	10/04/66	Rosaen	210	90		
	AE	3	3	3	2	9	5	0	7/67	Blumberg et al.	260	285		
	AF	3	4	9	3	6	5	7	2/70	Lewenstein et al.	424	260		
	AG	3	6	7	6	5	5	7	7/72	Lachman et al.	424	260		
	AH	3	7	7	3	9	5	5	11/73	Pachter et al.	424	260		
	AL	3	8	7	9	5	5	5	4/75	Pachter et al.	424	260		
FOREIGN PATENT DOCUMENTS														
		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
													YES	NO
	AJ	8	3	0	3	1	9	7	9/83	WO	A61K	9/22		
	AK	9	0	0	4	9	6	5	05/17/1990	WO	A61K	31/485		
	AL	9	8	0	6	4	2	6	3/94	WO	A61K	31/46		
	AM	9	5	0	3	8	0	4	2/95	WO	A61K	31/485		
	AN	9	6	0	2	2	5	1	2/96	WO	A61K	31/485		
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)														
	AD	Foss, J.F., et al. Abstract, "Prevention of Apomorphine- or Cisplatin- induced emesis in the dog by combination of Methylnaltrexone and Morphine", Cancer Chemother Pharmacol (1998); 42(4):287-91.												
	AP	Yuan et al., "Efficacy of Orally Administered Methylnaltrexone in Decreasing Subjective Effects After Intravenous Morphine", Drug and Alcohol Dependence (1998); 52:161-165.												
	AQ	Gan et al., "Opioid-Sparing Effects of a Low-Dose Infusion of Naloxone in Patient-Administered Morphine Sulfate," Anesthesiology (1997), 87(5):1075-1080.												
	AR	Shen et al., "Ultra-Low Doses of Naltrexone or Etorphine Increase Morphine's Antinociceptive Potency and Attenuate Tolerance/Dependence in Mice," Brain Research (1997), 757:176-190.												
	AS	Yuan et al., "The Safety and Efficacy of Oral Methylnaltrexone in Preventing Morphine-induced Delay in Oral-Cecal Transit Time", Clinical Trials and Therapeutics (1997), 61:467-475.												
	AT	Mendelson J., et al, "Buprenorphine and Naloxone Interactions in Opiate Dependent Volunteers," Clin. Phar. Ther. (1996), 60:105-114.												
	AU	Walsh et al., "Effects of Naltrexone on Response to Intravenous Cocain, Hydromorphone and their Combination in Humans," (1996).												
EXAMINER										DATE CONSIDERED				
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.														

FORM PTO-1449 (REV. 7-80)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE				ATTY. DOCKET NO.: 200.1113CON2		SERIAL NO.: 10/665,735						
<b>LIST OF PRIOR ART CITED BY APPLICANT</b>  (Use several sheets if necessary)						APPLICANT(S): Philip J. PALERMO et al.								
						FILING DATE: September 18, 2003		GROUP: 1614						
<b>U.S. PATENT DOCUMENTS</b>														
*EXAMINER INITIAL		DOCUMENT NUMBER							DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
	BA	3	9	1	6	8	8	9	11/04/1975	Russell	128	145.8		
	BB	3	9	6	5	2	5	6	06/22/1976	Leslie	424	22		
	BC	3	9	6	6	9	4	0	6/76	Pachter et al.	424	260		
	BD	4	1	7	6	1	8	6	11/79	Goldberg	424	260		
	BE	4	2	3	7	1	4	0	12/02/1980	Dudzinski	424	260		
<b>FOREIGN PATENT DOCUMENTS</b>														
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	BF	9	7	3	3	5	6	6	9/97	WO	A61K	9/20		
	BG	9	8	3	5	6	7	9	8/98	WO	A61K	31/485		
	BH	9	9	3	2	1	2	0	7/99	WO	A61K	31/485		
	BI	0	0	0	1	3	7	7	01/13/2000	WO	A61K	31/00		
	BJ	8	7	0	1	2	8	2	03/12/1987	WO	A61K	31/485		
<b>OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)</b>														
	BK	Chih-Cheng Chien, et al., "Sigma Antagonists Potentiate Opioid Analgesia in Rats", Neuroscience Letters 190 (1995), 137-139.												
	BL	Crain et al., "Ultra-Low Concentrations of Naloxone Selectively Antagonize Excitatory Effects of Morphine on Sensory Neurons, Thereby Increasing Its Antinociceptive Potency and Attenuating Tolerance/Dependence During Chronic Cotreatment," Proc. Natl. Acad. Sci. USA (1995) 92:10540-10544.												
	BN	Hanson, Analgesic, Antipyretic and Anti-Inflammatory Drugs in Remington's Science and Practice of Pharmacy (1995), 2:1207.												
	BO	Talwin NX, Physician's Desk Reference 48 <sup>th</sup> Ed. (1994) Montvale, NJ 2120-2121.												
	BP	Foss et al., "Dose related Antagonism of the Emetic Effect of Morphine by Methylnaltrexone in Dogs", J. Clin Pharmacol (1993), 33:747-751												
	BQ	Holmes et al., "Inhibiting Spinal Dynorphin A Component Enhances Intrathecal Morphine Antinociception in Mice", Anesth. Analg. (1993), 77:1166-73.												
	BR	Miakowski et al., "Inhibition of Spinal Opioid Analgesia by Supraspinal Administration of Selective Opioid Antagonists", Brain Research (1992), 30:263-274.												
EXAMINER										DATE CONSIDERED				
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FORM PTO-1449 (REV. 7-80)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE				ATTY. DOCKET NO.: 200.1113CON2		SERIAL NO.: 10/665,735						
<b>LIST OF PRIOR ART CITED BY APPLICANT</b>  (Use several sheets if necessary)						APPLICANT(S): Philip J. PALERMO et al.								
						FILING DATE: September 18, 2003		GROUP: 1614						
<b>U.S. PATENT DOCUMENTS</b>														
*EXAMINER INITIAL	CA	DOCUMENT NUMBER							DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
	CA	4	2	8	5	9	8	7	08/25/1981	Ayer, et al.	427	3		
	CB	4	3	6	6	3	1	0	12/28/1982	Leslie	536	56		
	CC	4	4	0	1	6	7	2	8/83	Portoghese et al.	424	260		
	CD	4	4	4	3	4	2	8	04/17/1984	Oshlack et al.	424	22		
	CE	4	4	5	1	4	7	0	5/84	Ganti	424	260		
	CF	4	4	5	7	9	3	3	7/84	Gordon et al.	424	260		
	CG	4	4	6	4	3	7	8	8/84	Hussain et al.	424	260		
<b>FOREIGN PATENT DOCUMENTS</b>														
		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
													YES	NO
	CH	0	1	3	2	1	8	0	05/10/2001	WO (A2)	A61K	31/485		
	CI	0	1	6	8	0	8	0	09/20/2001	WO (A2)	A61K	31/00		
	CJ	0	1	3	7	7	8	5	05/31/2001	WO (A2)	A61K			
	CK	0	1	5	2	8	5	1	07/26/2001	WO (A1)	A61K	31/485		
	CL	0	1	8	5	2	5	7	11/15/2001	WO (A2)	A61P			
<b>OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)</b>														
	CM	Weinhold et al., "Buprenorphine Alone and in Combination with Naltrexone in Non-Dependent Humans," Drug and Alcohol Dependence (1992), 30:263-274.												
	CN	Cappel et al., "Enhancement of Naloxone Induced Analgesia by Pretreatment with Morphine" Pharma. Bioch. & Behav. (1989), 34:425-427.												
	CO	Vaccarino et al., "Analgesia Produced by Normal Doses of Opioid Antagonists Alone and in Combination with Morphine", Pain (1989), 36:103-109.												
	CP	Gonzalez et al., "Naltrexone: A Review of its Pharmacodynamic and Pharmacokinetic Properties and Therapeutic Efficacy in the Management of Opioid Dependence," Drugs (1988), 35:192-213.												
	CQ	Sunshine, et al., "Analgesic Efficacy of Pentazocine Versus a Pentazocine-Naloxone Combination Following Oral Administration," Clin. J. Pain (1988), 4:35-40.												
	CR	Wang et al., "Crossover and Parallel Study of Oral Analgesics," J. Clin. Pharmacol (1981), 21:162-168.												
	CS	Translation of German patent application DE 43 25 465												
EXAMINER										DATE CONSIDERED				
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<b>U.S. PATENT DOCUMENTS</b>															
*EXAMINER INITIAL		DOCUMENT NUMBER								DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
	DA	4	5	7	3	9	9	5	3/86	Chen et al.	604	896			
	DB	4	5	4	2	8	3	5	4/86	Lewis et al.	514	282			
	DC	4	6	4	8	3	7	8	8/86	Pasternak	514	282			
	DD	1	6	6	1	4	9	2	4/87	Lewis et al.	514	282			
	DF	4	7	1	9	2	4	5	1/88	Goldberg	514	282			
	DF	1	7	9	0	0	4	8	3/88	Portoghese et al.	546	45			
	DG	4	7	6	0	0	6	5	7/88	Rzeszotarski et al.	514	282			
<b>FOREIGN PATENT DOCUMENTS</b>															
		DOCUMENT NUMBER								DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
														YES	NO
	DH	0	1	9	3	8	5	2	12/31/2001	WO (A2)	A61K	31/00			
	DI	0	9	1	3	1	5	2	6/99	EP	A61K	31/485			
	DJ	0	6	4	7	4	4	4	4/95	EP	A61K	31/485			
	DK	0	3	5	2	3	6	1	1/90	EP	A61K	31/485			
	DL	0	2	0	5	2	8	2	12/86	EP	A61K	9/22			
<b>OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)</b>															
	DM	Alvarez-Fuentes, et al. "Effectiveness of Repeated Administration of a New Ora Naltrexone Controlled-Release System in Morphine Analgesia"; J. Pharm Pharmacol (2001), 53:1201-1205.													
	DN	Alvarez-Fuentes, et al., "Preclinical Study of an Oral Controlled Release Naltrexone Complex in Mice"; J. Pharm Pharmacol (2000), 52:659-663.													
	DO	Archer, Sydney; "Historical Perspective on the Chemistry and Development of Naltrexone"; Naltrexone Research Monograph 28 (1980) p. 3-9.													
	DP	Baum et al., "The Impact of the Addition of Naloxone on the Use and Abuse of Pentazocine"; Public Health Reports (1987) Vol. 102, No. 4 p. 426-429.													
	DQ	Rapaka et al., "Discovery of Novel Opioid Medications"; NIDA Research Monograph 147 (1995) p. 55-83.													
	DR	Bloom et al., "Clinical Studies with Naloxone/Methadone in a Ratio of 1:20"; 5 <sup>th</sup> National Conference on Methadone Treatment (1973) Vol 2, p. 1342-1349.													
EXAMINER										DATE CONSIDERED					
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.															

FORM PTO-1449 (REV. 7-80)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE				ATTY. DOCKET NO.: 200.1113CON2		SERIAL NO.: 10/665,735						
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						FILING DATE: September 18, 2003		GROUP: 1614						
U.S. PATENT DOCUMENTS														
*EXAMINER INITIAL	EA	DOCUMENT NUMBER							DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
	EA	4	7	6	9	3	7	2	9/88	Kreek et al.	514	282		
	EB	4	7	8	5	0	0	0	11/88	Kreek et al.	514	282		
	EC	4	8	0	3	2	0	8	2/89	Pasternak	514	282		
	ED	4	8	0	6	3	4	1	2/89	Chien et al.	424	448		
	EE	4	8	0	6	5	4	3	2/89	Choi	514	464		
	EF	4	8	0	6	5	5	8	2/89	Wuest et al.	514	381		
	EG	4	8	2	8	8	3	6	05/09/1989	Elger et al.	424	419		
FOREIGN PATENT DOCUMENTS														
		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
													YES	NO
	EH	0	1	9	3	3	5	5	09/03/1986	EP (A3)	A61K	31/615		
	EI	0	3	1	9	2	4	3	06/07/1989	EP (A1)	A61K	31/485		
	EJ	0	3	1	9	2	4	3	11/07/1990	EP (B1)	A61K	31/485		
	EK	19	6	5	1	5	5	1	6/98	DE	A61K	31/485		
	EL	29	7	1	9	7	0	4	2/97	DE	A61K	31/485		
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)														
	EM	Briscoe et al., "Methoclocinnamox: Time Course of Changes in Alfentanil-Reinforced Rhesus Monkeys"; Psychopharmacology (2000) 148:393-399.												
	EN	Abstract of Bromm, et al., "A Sensitive Method to Evaluate Effects of Analgesics in Man"; Meth and Find Exptl Clin Pharmacol 5 (8) (1983) p. 545-551.												
	EO	Bullingham et al., "Clinical Pharmacokinetics of Narcotic Agonist-Antagonist Drugs"; Clinical Pharm (1983) 8: 332-343.												
	EP	Calimlim, et al. "Effect of Naloxone on the Analgesic Activity of Methadone in a 1:10 Oral Combination"; Clin Pharmacol and Ther (1974) Vol. 15; No. 6 pp.556-564.												
	EQ	Caruso et al., "Methadone and Naloxone in Combination (Naldone®) for the Treatment of Heroin Addicts"; Bristol Laboratories, pp.1336-1341F.												
	ER	Cherny, Nathan I., "Opioid Analgesics"; Drugs (1996) May;51 (5) pp. 713-737.												
	ES	Chiang, et al. "Clinical Evaluation of a Naltrexone Sustained-Release Preparation"; Drug and Alcohol Dependence (1985) 16, pp.1-8.												
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	FA	4	8	3	4	9	6	5	05/30/1989	Martani et al.	424	488		
	FB	4	8	3	4	9	8	4	05/30/1989	Goldie et al.	424	494		
	FC	4	8	3	4	9	8	5	05/30/1989	Elger et al.	424	494		
	FD	4	8	4	4	9	0	7	07/04/1989	Elger et al.	424	465		
	FE	4	8	4	4	9	9	9	07/04/1989	Goldie et al.	424	480		
	FF	4	8	4	4	9	1	0	07/04/1989	Leslie et al.	424	494		
	FG	4	8	6	4	5	9	8	8/89	Oshlak et al.	424	468		
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	FH	4	3	2	5	4	6	5	2/95	DE	A61K	31/485		x
	FI	2	2	2	2	0	3	9	11/72	DE	A61K	27/00		
	FJ	9	8	2	5	6	1	3	06/18/98	WO	A61K	31/485	abstract	
	FK	0	0	3	8	6	4	9	07/06/00	WO	A61K	9/00	abstract	
<b>OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)</b>														
	FL	Chiang et al., "Kinetics of a Naltrexone Sustained-Release Preparation"; Clin Pharmacol Thera (1984) Vol 36 No. 5, pp.704-708.												
	FM	Comer et al., "Depot Naltrexone: Long-lasting Antagonism of the Effects Of Heroin un Humans"; Psychopharmacology (2002) 159, pp.351-360.												
	FN	Crabtree et al., "Review of Naltrexone, a long-acting Opiate Antagonist"; Clinical Pharmacy, Vol. 3 (1984) pp.273-280.												
	FO	Crain et al., "Antagonists of Excitatory Opioid Receptor Functions Enhance Morphine's Analgesic Potency and Attenuate Opioid Tolerance/dependence liability"; Dept. of Neuroscience, Albert Einstein College of Medicine Pain 82 (1999)pp.1-11.												
	FP	Crain et al., "Antagonists of Excitatory Opioid Receptor Functions Enhance Morphine's Analgesic Potency and Attenuate Opioid Tolerance/dependence liability"; Dept. of Neuroscience, Albert Einstein College of Medicine Pain 84 (2000) pp.121-131.												
	FQ	Fink et al., "naloxone in Heroin Dependence"; Clin Pharm and Thera. Vol 9, No. 5;pp.568-577.												
	FR	Fishman et al., "Disposition of Naloxone-7,8- <sup>3</sup> H in Normal & Narcotic Dependent Men"; J. Pharm. And Exper. Thera (1973)Vol 10 No. 2;pp.575-580.												
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		4	8	0	1	7	8	1	8/89	Goldberg	514	282			
	GB	4	8	6	7	9	8	5	09/19/1989	Heafield et al.	424	461			
	GC	4	8	7	3	0	2	6	10/89	Fishman et al.	412	10			
	GD	4	8	8	2	3	3	5	11/89	Sinclair	514	282			
	GE	4	8	0	9	8	6	0	12/89	Rzeszolarski et al.	514	282			
	GF	4	9	3	5	4	2	8	6/90	Lewis	514	282			
	GG	4	9	4	0	9	8	7	07/10/1990	Jenkins et al.	424	480			
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	GH	00	1	5	8	4	7	7	8/16/01	WO	A61P			abstract	
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	GI	Fraser, Albert D., et al., "Clinical Toxicology of Drugs Used in the Treatment of Opiate Dependency"; Clinical Toxicology I (1990) Vol 10, No. 2; pp.375-386.													
	GJ	Freye et al., "Effects of Tramadol and Tilidine/Naloxone on Oral-Caecal Transit & Pupillary light Reflex"; Arzneim-Forsch/Drug Res. 50(I)(2000)pp. 24-30.													
	GK	Fudala, et al., "Effects of Buprenorphine asnd Naloxone in Morphine-Stabilized Opioid Addicts"; Drug and Alcohol Dependence 50 (1998) pp. 1-8.													
	GL	Fudala et al., "Human Pharmacology and Abuse Potential Of Nalmefene"; Clin Pharm and Thera (1991) Vol 49, 3, pp. 300-306.													
	GM	Gal et al., "Prolonged Blockade of Opioid Effect with Oral Nalmefene"; Clin Pharm and Thera (1986) pp. 537-542.													
	GN	Gerra et al., "Clonidine and Opiate Receptor Antagonists in the Treatment of Heroin Addiction"; J. Substance Abuse Treatment (1995) Vol 12, 1, pp. 35-41.													
	GO	Ghodse, et al., "Opioid analgesics and Narcotic Antagonists"; Side Effects of Drugs (2000) Annual 23, chpt 8 pp. 96-113.													
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	HA	4	2	0	0	0	9	8	04/29/1980	Ayer, et al.	128	260		
	HB	4	9	7	0	0	7	5	11/13/1990	Oshlak	424	451		
	HC	4	9	8	7	1	3	6	01/22/1991	Kreek et al.	514	282		
	HD	4	0	9	0	3	4	1	02/05/1991	Goldie et al.	424	484		
	HE	5	0	7	4	0	4	6	12/10/1991	Malkowska et al.	424	497		
	HE	5	0	7	5	3	4	1	12/91	Mendelson et al.	514	282		
	HG	5	0	8	6	0	5	8	2/92	Sinclair et al.	514	282		
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	HH	00	1	8	5	1	5	0	11/15/01	WO	A61K	31/00		
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)														
	HI	Glatt, William, M.D. FACP, "A New Method for Detoxifying Opioid-Dependent Patients"; J. Substance Abuse Treatment (1999) Vol.17, No.3, pp. 193-197												
	HJ	Gold, et al. "Rapid Opioid Detoxification During General Anesthesia"; Anesthesiology (1999) Vol 91, No 6, pp. 1639-1647.												
	HK	Greenwald, et al., "Comparative Clinical Pharmacology of Short-Acting $\mu$ Opioids in Drug Abusers"; J. Pharm and Exper Thera (1996) Vol 277, No 3, pp. 1228-1236.												
	HL	Gupta, et al., "Morphine Combined with Doxapram or Naloxone"; Anesthesia (1974) Vol 29, pp. 33-39.												
	HM	Richter et al., "Clinical Investigation on the Development of Dependence during Oral Therapy with Tramadol"; Arzneim-Forsch/Drug Res. 35 (No II)(1985)pp. 1742-1744.												
	HN	Rosen et al., "The effect of Lamotrigine on Naloxone-precipitated Opiate withdrawal"; Drug and Alcohol Dependence (1998) Vol 52, pp. 173-176.												
	HO	Rosen et al., "A Pilot Study of Dextromethorphan in Naloxone-Precipitated Opiate Withdrawal"; European J. of Pharm. (1996) Vol 307, pp. 251-257.												
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	IA	5	3	9	1	1	8	9	02/25/1992	Heafield et al.	424	457		
	IB	5	0	9	8	7	1	5	9/92	Sinclair	424	438		
	IC	5	1	6	2	8	8	7	4/92	Goldberg	514	282		
	ID	4	1	6	0	0	2	0	07/03/1979	Ayer, et al.	424	15		
	IE	5	1	4	9	5	3	8	9/92	Granger et al.	424	449		
	IE	5	2	1	5	7	5	8	06/01/1993	Krishnamurthy	424	488		
	IG	5	2	2	5	4	4	0	7/93	London et al.	514	535		
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	IH	00	0	6	7	7	3	9	11/16/00	WO	A61K	31/00		
<b>OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)</b>														
	IJ	Schuh et al., "Buprenorphine, Morphine and Naloxone Effects during Ascending Morphine Maintenance in Humans"; J. Pharm and Exper Thera (1996) Vol 278, 2, pp. 836-846.												
	IK	Schuh et al., "Onset, Magnitude and Duration of Opioid Blockade Produced by Buprenorphine and Naltrexone in Humans"; Psychopharmacology (1999) Vol 145, pp. 162-174.												
	IL	Stevens et al., "Nonspecific Excitatory Effects of Morphine: Reverse-Order Precipitated Withdrawal and Dose-Dose Interactions"; Psychopharmacology (1981) Vol 75, pp. 210-211.												
	IM	Stine et al., "Reduction of Opiate Withdrawal-like Symptoms by Cocaine Abuse during Methadone and Buprenorphine Maintenance"; Am. J. Drug and Alcohol Abuse (1994) Vol 20, 4, pp. 445-458.												
	IN	Stine et al., "Use of Drug Combinations in Treatment of Opioid Withdrawal"; J. Clinical Psych. (1992) Vol 12, No 3, pp. 203-209.												
	IO	Stoller et al., "Effects of buprenorphine/naloxone in opioid-dependent humans" Psychopharmacology (2001) Vol 154, pp. 230-242.												
	IP	Strain et al., "Acute Effects of Buprenorphine, hydromorphone and naloxone in methadone-maintained volunteers"; J. Pharm and Exper Thera (1992) Vol 261, No 3, pp. 985-993.												
	IQ	Strain et al., "Effects of buprenorphine versus buprenorphine/naloxone tablets in non-dependent opioid abusers"; Psychopharmacology (2000) Vol 148, pp. 374-383.												
	IR	Strain et al., "Precipitated Withdrawal by Pentazocine in Methadone-Maintained Volunteers"; J. Pharm and Exper Thera (1993) Vol 267, No 2, pp. 624-634.												
	IS	Tai, et al., "Naltrexone: An Antagonist Therapy for Heroin Addiction"; NIDA (1997) 5 pages												
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	JA	5	2	2	6	3	3	1	07/13/1993	Thompson et al.	73	865.9		
	JB	5	2	3	6	7	1	4	8/93	Lee et al.	424	449		
	JC	5	2	5	6	6	6	9	10/93	Askanazi et al.	514	282		
	JD	5	2	6	6	3	3	1	11/30/1993	Oshlak et al.	424	468		
	JE	5	2	7	3	7	6	0	12/93	Oshlak et al.	424	486		
	JF	5	2	8	6	4	9	3	02/15/1994	Oshlak et al.	424	468		
	JG	5	3	1	6	7	5	9	12/93	Rose et al.	424	10		
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	JH	00	0	5	1	5	9	2	9/05/00	WO	A61K	31/14		
<b>OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)</b>														
	JI	Umbricht et al., "Naltrexone shortened opioid detoxification with buprenorphine"; Drug and Alcohol Dependence (1999) Vol 56 pp. 181-190												
	JK	Vaccarino et al., "Enogenous Opiates: 1999"; Peptides 21 (2000) pp. 1975-2034.												
	JL	Wang et al., "Inverse Agonists and neutral antagonists at $\mu$ opioid receptor (MOR): possible role of basal receptor signaling in narcotic dependence"; J. Neurochemistry (2001) Vol 77, pp. 1590-1600.												
	JM	Way et al., "Responsivity to Naloxone during Morphine Dependence"; Annals New York Academy of Sciences, pp. 252-261.												
	JN	Weinberg et al., "Sublingual absorption of selected opioid analgesics"; Clin Pharm Thera (1988) Vol 44, No 3, pp. 335-342.												
	JO	Wells, et al., "In vivo Pharmacological Characterization of SoRI 9409, a Nonpeptidic Opioid $\mu$ -Agonist/ $\delta$ -Antagonist that Produces Limited Antinociceptive Tolerance and Attenuates Morphine Physical Dependence"; J. Pharm and Exper Thera (2001) Vol 297, No 2, pp. 597-605												
	JP	Wodak, Alex, "Drug Treatment for Opioid Dependence"; Australian Prescriber (2001) Vol 24, No 1, pp. 4-6.												
	JQ	Wright et al., "Acute physical dependence in Humans; repeated naloxone-precipitated withdrawal after a single-dose of methadone"; Drug and Alcohol Dependence (1991) Vol 27, pp. 139-148.												
	JR	Zhu et al., "Naltrexone-precipitated morphine withdrawal in infant rat is attenuated by acute administration of NOS inhibitors but not NMDA receptor antagonists"; Psychopharmacology (2000) Vol 150, pp. 325-336.												
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	KA	5	3	1	7	0	2	2	5/94	Borsodi et al.	514	282	
	KB	5	3	2	1	0	1	2	6/94	Mayer et al.	514	25	
	KC	5	3	2	4	3	5	1	06/28/1994	Oshlak et al.	106	153	
	KD	5	3	3	6	8	0	1	08/09/1994	Raffa et al.	514	629	
	KE	5	3	5	2	8	0	0	10/94	Portoghese et al.	514	279	
	KF	5	3	5	2	6	8	3	10/94	Mayer et al.	514	289	
	KG	5	3	5	6	4	6	7	10/18/1994	Oshlak et al.	106	153	
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	KH	0	1	5	8	4	5	1	08/19/2001	WO (A1)	A61K	31/485	
<b>OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)</b>													
	KI	Han et al., "Mucocoadhesive buccal disks for novel nalbuphine prodrug controlled delivery; effect of formulation variable on drug release and mucocoadhesive performance"; International J. Pharm (1999) Vol 177, pp. 201-209.											
	KJ	Handal et al., "Naloxone"; Annals of Emergency Medicine (1983) Vol 12:7, pp. 438-445.											
	KK	Harris et al., "Buprenorphine and Naloxone co-administration in opiate dependent patients stabilized on sublingual buprenorphine"; Drug and Alcohol Dependence (2000) Vol 61, pp. 85-94.											
	KL	Hawkes et al., "Effect of enteric-release formulation of naloxone on intestinal transit in volunteers taking codeine"; Aliment Pharm Ther (2001) Vol 15, pp. 625-630.											
	KM	Högger et al., "Comparison of tilidine/naloxone, tramadol and bromfenac in experimental pain: a double-blind randomized crossover study in healthy human volunteers"; International J. Clin Pharm and Thera (1999) Vol 37, No 8, pp. 377-385											
	KN	Budd, Keith, "Clinical Use of Opioid Antagonists"; Bailliere's Clinical Anesthesiology (1987) Vol 1, No 4, pp. 993-1011.											
	KO	Crain et al., "Ultra-low concentrations of naloxone selectively antagonize excitatory effects of morphine on sensory neurons, thereby increasing its antinociceptive potency and attenuating tolerance/dependence											
	KP	Howes et al., "The Pharmacology of TR5109, a new Narcotic Agonist/Antagonist Analgesic"; NIDA Research (1979) pp. 99-105.											
	KQ	Leeling et al., "Disposition and metabolism of codorphone in the rat, dog, and man"; Drug Metabolism and Disposition (1982) Vol 10, No 6, pp 649-653.											
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	LA	5	3	5	6	9	0	0	12/94	Bihari et al.	514	282		
	LB	5	3	7	6	6	6	2	12/94	Ockert	514	282		
	LC	3	5	4	1	0	0	5	11/17/1970	Strathmann, et al.	210	19		
	LD	5	4	1	1	7	4	5	05/02/1995	Oshlack et al.	424	456		
	LC	5	4	2	6	1	1	2	06/95	Zagon et al.	514	282		
	LF	8	5	4	1	0	0	4	11/17/1970	Bixler, et al.	210	23		
	LG	5	4	5	7	2	0	4	10/95	Portoghese et al.	546	35		
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<b>OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)</b>														
	LI	Amass et al., "Efficacy of daily and alternate-day dosing regimens with the combination buprenorphine-naloxone tablet"; Drug and Alcohol Dependence (2000) Vol 58, pp. 143-152.												
	LJ	Hassain et al., "Buccal and oral bioavailability of naloxone and naltrexone in rats"; (1987) Vol 36, pp. 127-130.												
	LK	Jasinski et al., "The human pharmacology and abuse potential of N-allylnoroxymorphone naloxone"; J. Pharm and Exper Thera (1967) Vol 157, No 2, pp. 420-426.												
	LM	Jones et al., "Nalmefene: blockade of intravenous morphine challenge effects in opioid abusing humans"; Drug and Alcohol Dependence (2000) Vol 60, pp. 29-37.												
	LN	Kanof et al., "Clinical Characteristics of Naloxone-Precipitated Withdrawal in Human Opioid-Dependent Subjects"; J Pharma and Exper Thera (1992) Vol 260, No. 1, pp. 355-363.												
	LO	King et al., "Naltrexone Biotransformation and Incidence of Subjective Side Effects: A Preliminary Study"; Alcoholism: Clin and Exper Res (1997) Vol 21, No 5, pp. 906-909.												
	LP	Kogan et al., "Estimation of the Systemic Availability and Other Pharmacokinetic Parameters of Naltrexone in Man after Acute and Chronic Oral Administration"; Res. Comm. In Chem. Path. And Pharm (1977) Vol 18, No. 1, pp 29-34.												
	LQ	Kosten, Thomas R., M.D., "Buprenorphine for Benzodiazepine-Abusing Heroin Addicts"; Amer J of Psychiatry (1994) Vol 1, p 151.												
	LR	Kosten et al., "Opioid antagonist challenges in buprenorphine maintained patients"; Drug and Alcohol Dependence (1990) Vol 25, OO. 73-78.												
	LS	Kurland et al., "Naloxone and the Narcotic Abuser: A Controlled Study of Partial Blockade"; Inter. J. of the Addictions (1974) Vol 9, No 5, pp. 663-672.												
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<b>U.S. PATENT DOCUMENTS</b>													
*EXAMINER INITIAL		DOCUMENT NUMBER						DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
	MA	5	4	4	3	8	2	6	10/24/1995	Merrill et al.	424	470	
	MB	5	4	7	2	7	1	7	12/05/1995	Oshlack et al.	424	480	
	MC	5	4	7	2	9	4	3	12/95	Crain et al.	514	12	
	MD	5	4	7	8	5	7	7	12/26/1995	Sackler et al.	424	489	
	ME	5	4	8	6	3	6	2	1/96	Kitchell et al.	424	426	
	ME	5	5	0	6	2	2	7	03/19/1996	Oshlack et al.	424	476	
<b>FOREIGN PATENT DOCUMENTS</b>													
		DOCUMENT NUMBER						DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
												YES      NO	
	MG												
<b>OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)</b>													
	MH	Lee et al., "Nalbuphine Coadministered with Morphine Prevents Tolerance and Dependence"; Anesth Analg (1997) Vol 84, pp.810-815											
	MI	Lehman, et al., "Influence of Naloxone on the Postoperative Analgesic and Respiratory effects of Buprenorphine"; Eur. J. Clin Pharm (1988) Vol 34, pp. 343-352.											
	MJ	Levine et al., "Potentiation of Pentazocine Analgesia by Low-dose Naloxone"; J Clin Invest (1988) Vol 82, pp. 1574-1577.											
	MI	Loimer et al., "Combined Naloxone/Methadone Preparations for Opiate Substitution Therapy"; J. of Substance Abuse Treatment (1991) Vol 8, pp. 157-160.											
	ML	Martin et al. "Bioavailability Investigation of a New Tilidine/Naloxone Liquid Formulation Compared to a Reference Formulation"; Arzneimittel-Forsch./Drug Res. (1999) Vol 49, pp. 599-607.											
	MM	Martin et al., "Demonstration of Tolerance to and Physical Dependence on N-allylnormorphine (Nalorphine)"; J. Of Pharm and Exper Thera (1965) Vol 150, No 3. Pp. 437-442.											
	MN	Mendelson et al., "Buprenorphine and naloxone combinations: the effects of three dose ratios in morphine stabilized, opiate-dependent volunteers"; Psychopharmacology (1999) Vol 141, pp. 37-46.											
	MO	Mendelson et al., "Buprenorphine and naloxone Interactions in Methadone Maintenance Patients"; Society of Biological Psychiatry (1997) Vol 41, pp. 1095-1101.											
	MP	Nutt et al., "Methadone-naloxone mixture for use in methadone maintenance programs"; Clin Pharm and Ther. Vol 15, No 2., pp 156-166											
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<b>LIST OF PRIOR ART CITED BY APPLICANT</b>  (Use several sheets if necessary)						APPLICANT(S): Philip J. PALERMO et al.							
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*EXAMINER INITIAL	NA	DOCUMENT NUMBER				DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE			
		5	5	0	2	0	5	8	3/96	Mayer et al.	514	289	
	NB	5	5	0	8	0	4	2	04/16/1996	Oshlack et al.	424	468	
	NC	5	5	0	8	0	4	3	04/16/1996	Krishnamurthy	424	484	
	ND	5	5	1	2	5	7	8	4/96	Crain et al.	514	282	
	NE	5	5	1	4	6	8	0	5/96	Weber et al.	514	249	
<b>FOREIGN PATENT DOCUMENTS</b>													
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										YES	NO		
	NF												
<b>OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)</b>													
	NG	Parwatikar et al., "Methadone-naloxone in combination for the Treatment of Heroin Addicts"; Clin. Pharm and Thera, Vol 14, No. 6, pp 941-948.											
	NH	Parwartikar et al., "Naloxone-Methadone Combination for the Treatment of Opiate Dependence"; Missouri Institute of Psychiatry, pp. 1350-1354.											
	NI	Pitts et al., "Antinociceptive and Response Rate-Altering Effects of <i>Kappa</i> Opioid Agonists, Spiradoline, Enadoline and U69,593, Alone and in Combination with Opioid Antagonists in Squirrel Monkeys"; J of Pharm and Exper Thera (1994) Vol 271, No 3, pp. 1501-1508.											
	NJ	Preston et al., "Buprenorphine and Naloxone alone and in combination in Opioid-dependant Humans"; Psychopharmacology (1988), Vol 94, pp. 484-490.											
	NK	Preston et al., "Differential Naltrexone Antagonism of Hydromorphone and Pentazocine Effects in Human Volunteers"; J of Pharm and Ezper Thera (1993) Vol 264, No 2 pp. 813-823.											
	NL	Preston et al., "Effects of Sublingually given naloxone in Opioid -dependant human volunteers"; Drug and Alcohol Dependence (1990) Vol 25, pp. 27-34.											
	NM	Bigelow et al., "Abuse Liability and Assessment of Buprenorphine-Naloxone Combinations"; Dept of Psychiatry and Behavioral Sciences, The Johns Hopkins University School of Medicine, pp. 145-149.											
	NN	Wikler et al., "N-Allylnormorphine: Effects of single dose and Precipitation of Acute "Abstinence Syndromes" during addiction to morphine, methadone or heroin in man (post addicts)"; N-Allylnormorphine During Narcotic Addiction (1953) pp. 8-20.											
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*EXAMINER INITIAL		DOCUMENT NUMBER							DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
	OA	5	5	3	4	4	9	2	7/96	Aston et al.	514	608		
	OB	5	5	4	9	9	1	2	08/27/1996	Oshlack et al.	424	468		
	OC	5	5	5	2	4	2	2	09/03/1996	Gauthier et al.	514	368		
	OD	5	5	5	6	8	3	8	9/96	Mayer et al.	514	25		
	OE	5	5	7	4	0	5	2	11/96	Rose et al.	514	343		
<b>FOREIGN PATENT DOCUMENTS</b>														
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													YES	NO
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<b>OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)</b>														
	OG	Zaks et al., "Naloxone Treatment of Opiate Dependence"; JAMA (1971) Vol 215, No 13, pp. 2108-2110.												
	OH	Barton, et al., "Intranasal Administration of Naloxone by Paramedics"; Prehospital Emergency Care (2002) Vol 6, No 1, pp. 54-58.												
	OI	Blachly, Paul, H., M.D., "Naloxone in Opiate Addiction"; Current Psychiatric Therapies (1976) pp. 209-213.												
	OJ	Bashaw et al., "Relative bioavailability of controlled-release oral morphine sulfate during naltrexone blockade"; Inter J of Clin Pharm and Thera (1995) Vol 33, No 9, 524-529.												
	OK	Jasinski, D.R., "Assessment of the Abuse Potential of Morphinelike Drugs (Methods Used in Man)"; Drug Addiction (1977) pp. 197-258.												
	OL	Johnson et al., "Buprenorphine and Naloxone for Heroin Dependence"; Substance Use Disorders (2000) pp. 519-526.												
	OM	Strain et al., "Opioid antagonist effects of dezocine in opioid-dependent humans"; Clin Pharm and Thera (1996) Vol 60, No 2, pp. 206-217.												
	ON	Preston et al., "Abuse liability and studies of opioid agonist-antagonists in humans"; Drug and Alcohol Dependence (1991) vol 28, pp. 49-82.												
	OO	Brennscheidt et al., "Pharmacokinetics of Nortilidine and Naloxone after Administration of Tilidine/Naloxone Solution or Tilidine/Naloxone Sustained Release Tablets"; Arznei-Forsch/Drug Res. (2000) Vol 50, pp. 1015-1022.												
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*EXAMINER INITIAL	PA	DOCUMENT NUMBER							DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
	PA	5	5	7	8	7	2	5	11/96	Portoghese et al.	546	35		
	PB	5	5	8	0	8	7	6	12/96	Crain et al.	514	282		
	PC	5	5	8	5	3	4	8	12/96	Crain et al.	514	12		
	PD	5	5	9	1	4	5	2	01/04/1997	Miller et al.	424	468		
	PE	5	6	0	1	8	4	5	02/11/1997	Buxton et al.	424	495		
<b>FOREIGN PATENT DOCUMENTS</b>														
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													YES	NO
	PF													
<b>OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)</b>														
	PG	Benfey, "Function of Myocardial $\alpha$ -Adrenoceptors"; Life Sciences (1982) vol 31, pp. 101-112.												
	PH	Levine et al., "Potentiation of Pentazocine Analgesia by Low-dose Naloxone"; J of Clin Invest. (1988) Vol 82, pp. 1547-1577.												
	PI	Yoburn et al., "Opioid Antagonist-induced Receptor Upregulation: Effects of Concurrent Agonist Administration"; Brain Research Bulletin (1994), Vol 33, pp. 237-240.												
	PJ	Bunzow et al., "Molecular Cloning and Tissue Distribution of a Putative Member of the Rat Opioid Receptor Gene Family that is not a $\mu$ , $\delta$ , or $\kappa$ opioid receptor type"; FEBS letters (1994) pp. 284-288.												
	PK	Mollereau et al., "ORL 1, a novel member of the opioid receptor family: Cloning, functional expression and localization"; FEBS letters 341 (1994), pp. 33-38.												
	PL	Wang, et al., "cDNA cloning of an orphan opiate receptor gene family member and its splice variant"; FEBS letters 348 (1994) pp. 75-79.												
	PM	Suzuki et al., "Morphine conditioned place preference after chronic treatment with naloxone in the rat"; Research Communications in Substance Abuse (1991) vol 12, No 3, pp. 119-131.												
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	QA	5	6	1	6	6	0	1	4/97	Khanna et al.	514	399		
	QB	5	6	2	2	7	2	2	04/22/1997	Knott et al.	424	494		
	QC	5	6	2	4	9	3	2	4/97	Qin et al.	514	282		
	QD	5	6	3	3	2	5	9	5/97	Qin et al.	514	282		
	QE	5	6	3	9	4	7	6	06/17/1997	Oshlack et al.	424	468		
<b>FOREIGN PATENT DOCUMENTS</b>														
		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
													YES	NO
	QF													
<b>OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)</b>														
	QG	Press Release "International Patent Application to Be Published on Abuse-Resistant Pain Reliever Being Developed by Perdue Pharma"; August 8, 2001.												
	QH	Paronis et al., "Increased Analgesic Potency of Mu Agonists after Continuous Naloxone Infusion in Rats"; J of Pharm Exper Thera (1991), 259 (2), pp. 582-589.												
	QI	Yoburn et al., "Supersensitivity to Opioid Analgesics Following Chronic Opioid Antagonist Treatment: Relationship to Receptor Sensitivity"; Pharmacology Bio Beh (1995) Vol 51 No. 2, pp. 535-539.												
	QJ	Crain et al., "Acute thermal hyperalgesia elicited by low-dose morphine in normal mice is blocked by ultra-low-dose naltrexone, unmasking potent opioid analgesia"; Brain Research (2001) Vol 888, pp. 75-82.												
	QK	Zhang et al., "Down-Regulation of $\mu$ -Opioid Receptors in Rat and Monkey Dorsal Root Ganglion Neurons and Spinal Cord After Peripheral Axotomy"; Neuroscience (1998) Vol 82, pp. 223-240.												
	QL	Abdulla et al., "Axotomy reduces the effect of analgesic opioids yet increases the effect of nociceptin on dorsal root ganglion neurons"; J of Neuro Sci (1998) Vol 18, pp 9685-9694.												
	QM	Di Giannuario et al., "Orphanin FQ reduces morphine-induced dopamine release in the nucleus accumbens: a microdialysis study in rats"; Neurosci. Lett (1999) Vol 272 pp. 183-186.												
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	RA	5	6	5	6	2	9	5	08/12/1997	Oshalck et al.	424	468		
	RB	5	6	7	0	1	7	7	09/23/1997	Buxton et al.	424	490		
	RC	5	6	7	2	3	0	0	09/30/1997	Sackler et al.	424	490		
	RD	5	6	8	1	5	8	5	10/28/1997	Oshalck et al.	424	494		
	RE	5	7	0	3	4	5	2	06/09/1998	Miller et al.	514	282		
	RI	5	7	6	7	1	2	5	06/98	Crain et al.	514	282		
	RG	5	7	8	0	4	7	9	07/14/1998	Kim	514	282		
	RH	5	7	6	7	1	2	5	06/16/1988	Crain, et al.	514	282		
	RI	6	0	9	6	7	5	6	08/01/2000	Crain, et al.	514	282		
	RJ	6	1	9	4	3	8	2	02/27/01	Crain, et al.	514	2		
	RK	6	3	6	2	1	9	4	03/26/2002	Crain, et al.	514	285		
	RL	6	3	9	5	7	0	5	05/28/2002	Crain, et al.	514	2		
	RM	20	01	00	06	9	6	7	07/05/2001	Crain, et al.	514	253.04		
	RN	20	01	00	18	4	1	3	08/30/2001	Crain, et al.	514	2		
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	RO													
<b>OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)</b>														
	RP	Ciccocioppo et al., "Effect of Nociceptin/orphanin FQ on the Rewarding Properties of Morphine"; Eur. J Pharmacol (2000) Vol 404, pp. 153-159.												
	RQ	Physician's Desk Reference (2001) see Revia, pp. 1146-1149 and Oxycontin, pp. 2697-2701												
	RR													
	RS													
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	SA	5	8	1	1	1	2	6	09/22/1998	Krishnamurthy	424	443		
	SB	5	8	3	4	4	7	7	11/10/1998	Mioduszewski	514	282		
	SC	5	8	4	3	4	8	0	12/01/1998	Miller et al.	424	484		
	SD	5	8	4	9	2	4	0	12/15/1998	Miller et al.	264	460		
	SE	5	8	5	8	0	1	7	1/99	Demopoulos et al.	604	890.1		
	SF	5	8	6	0	9	5	0	1/99	Demopoulos et al.	604	49		
	SG	5	8	6	6	1	6	4	2/99	Kuczynski et al.	424	472		
	SH	5	4	0	9	9	4	4	04/25/1995	Black et al.	514	359		
	SI	5	1	3	0	3	1	1	07/14/1992	Guillaumet et al.	514	234.2		
	SJ	4	4	0	1	6	7	2	08/30/1983	Portoghese	424	260		
	SK	4	4	5	7	9	3	3	07/03/1984	Gordon et al.	424	260		
	SL	5	4	3	6	2	6	5	07/25/1995	Black et al.	514	420		
	SM	5	6	3	9	7	8	0	06/17/1997	Lau et al.	514	419		
	SN	5	6	0	4	2	6	0	02/18/1997	Guay et al.	514	605		
	SO	5	6	0	4	2	5	3	02/18/1997	Lau et al.	514	415		
	SP	5	5	9	3	9	9	4	01/14/1997	Batt et al.	514	252		
	SQ	5	5	3	6	7	5	2	07/16/1996	Ducharme et al.	514	602		
	SR	5	5	5	0	1	4	2	08/27/1996	Ducharme et al.	514	359		
	SS	5	5	2	1	2	1	3	05/28/1996	Prasit et al.	514	443		
	ST	5	5	1	0	3	6	8	04/23/1996	Lau et al.	514	419		
	SU	5	4	7	4	9	9	5	12/12/1995	Ducharme et al.	514	241		
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	TA	5	8	6	9	0	9	7	02/09/1999	Wong et al.	424	473			
	TB	5	8	7	9	7	0	5	03/09/1999	Heafield et al.	424	464			
	TC	5	8	8	0	1	3	2	3/99	Hill	514	282			
	TD	5	8	9	1	4	7	1	04/06/1999	Miller et al.	424	468			
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	TF	5	9	4	2	2	4	1	8/99	Chasin et al.	424	426			
	TG	5	9	5	8	4	5	2	09/28/1999	Oshlack et al.	424	457			
	TH	3	8	4	5	7	7	0	11/05/1974	Theeuwes et al.	128	260			
	TI	4	0	6	3	0	6	4	12/13/1977	Saunders et al.	219	121			
	TJ	4	0	8	8	8	6	4	05/09/1978	Theeuwes et al.	219	121			
	TK	4	2	9	3	5	3	9	10/06/1981	Ludwig et al.	429	19			
	TL	4	9	5	7	6	8	1	09/18/1990	Klimesch et al.	264	211.23			
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	UB	5	9	6	5	1	6	1	10/12/1999	Oshlack et al.	424	457		
	UC	5	9	6	5	1	6	3	10/12/1999	Miller et al.	424	468		
	UD	5	9	6	8	5	4	7	10/99	Reder et al.	424	449		
	UE	5	9	6	8	5	5	1	10/19/1999	Oshlack et al.	424	456		
	UF	5	9	7	2	9	5	4	10/99	Foss	514	282		
	UG	5	9	9	8	4	3	4	12/99	Mitch et al.	514	210.16		
	UH	3	1	7	3	8	7	7	03/16/1965	Jackson et al.	252	138		
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<small>*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.</small>														

FORM PTO-1449 (REV. 7-80)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE				ATTY. DOCKET NO.: 200.1113CON2		SERIAL NO.: 10/665,735						
<b>LIST OF PRIOR ART CITED BY APPLICANT</b>  (Use several sheets if necessary)						APPLICANT(S): Philip J. PALERMO et al.								
						FILING DATE: September 18, 2003		GROUP: 1614						
<b>U.S. PATENT DOCUMENTS</b>														
*EXAMINER INITIAL		DOCUMENT NUMBER							DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
	VA	6	0	2	4	9	8	2	02/15/2000	Oshlack et al.	424	476		
	VB	6	0	6	8	8	5	5	05/30/2000	Leslie et al.	424	468		
	VC	6	0	7	7	5	3	2	06/20/2000	Malkowska et al.	424	457		
	VD	6	0	7	7	5	3	3	06/20/2000	Oshlack et al.	424	461		
	VE	6	1	0	3	2	5	8	08/15/2000	Simon	424	449		
	VF	6	1	0	3	2	6	1	08/15/2000	Chasin et al.	424	459		
	VG	6	1	4	3	3	2	2	11/07/2000	Sackler et al	424	459		
<b>FOREIGN PATENT DOCUMENTS</b>														
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	VH													
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*EXAMINER INITIAL		DOCUMENT NUMBER							DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
	WA	6	1	4	3	3	2	8	11/07/2000	Heafield et al.	424	489		
	WB	6	1	6	2	4	6	7	12/19/2000	Miller et al.	424	468		
	WC	6	2	1	0	7	1	4	04/03/2001	Oshlack et al.	424	476		
	WD	6	2	2	8	8	6	3	05/08/2001	Palermo et al.	514	282		
	WE	6	2	5	4	8	8	7	07/03/2001	Miller et al.	424	468		
	WF	6	2	6	1	5	9	9	07/17/2001	Oshlack et al.	424	457		
	WG	6	2	7	7	3	8	4	08/21/2001	Kaiko et al.	424	400		
<b>FOREIGN P/TENT DOCUMENTS</b>														
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<b>U.S. PATENT DOCUMENTS</b>															
*EXAMINER INITIAL		DOCUMENT NUMBER							DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE		
	XA	6	2	9	4	1	9	5	09/25/2001	Oshlack et al.	424	457			
	XB	6	3	0	6	4	3	8	10/23/2001	Oshlack et al.	424	468			
	XC	6	3	2	6	0	2	7	12/04/2001	Miller et al.	424	468			
	XD	6	3	3	5	0	3	3	01/01/2002	Oshlack et al.	424	468			
	XE	6	3	7	5	9	5	7	04/23/2002	Kaiko et al.	424	400			
	XF	6	3	9	7	4	0	4	05/14/2002	Oshlack et al.	424	480			
	XC	6	3	9	9	0	9	6	06/04/2002	Miller et al.	424	464			
	XH	6	4	7	5	4	9	4	11/05/2002	Kaiko et al.	424	400			
	XI	6	6	2	7	6	3	5	09/30/2003	Palermo, et al.	514	282			
	XI	6	7	1	6	4	4	9	04/06/2004	Oshlack, et al.	424	449			
	XK	6	6	9	6	0	8	8	02/24/2004	Oshlack et al.	424	465			
	XL	6	6	9	6	0	6	6	02/24/2004	Kaiko et al.	424	400			
<b>FOREIGN PATENT DOCUMENTS</b>															
		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION		
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